REMARKS

Rejection Under 35 USC §112, second paragraph

The Examiner has rejected Claims 1-4, 6-11, 13-17, 19-23 and 25-26 on the ground that they are indefinite for failing to particularly point out and distinctly claim the subject matter which is regarded as the invention. Specifically, the Examiner objects to Claims 1, 8, 14 and 20 on the ground that they are unclear how "the detection of a globin-antiglobin complex is accomplished by immobilizing said complex using an immobilized capture molecule" (pending office action, paragraph 4). The Examiner seems to regard this as a capturing step and not a detection step. The Applicants disagree. However, in order to solely advance the business interests of the Applicants, and while retaining the right to prosecute the same or similar claims in the future, the Applicants have amended the appropriate independent claims to overcome this objection.

Further, the Examiner objects to these claims as being vague because "it is unclear where on the test matrix the immobilized capture molecule is located." The Applicants disagree. The wording of the claims make it clear that the immobilized capture molecule is located in the second region of the test matrix.

The Examiner also objects to Claim 20 as being vague and indefinite because the Examiner believes that the wording of the claim is directed towards the diagnosis of a symptom of a disease condition rather than a disease condition itself, as recited in the preamble to the claim. The Applicants disagree. However, in order to solely advance the business interests of the Applicants, and while retaining the right to prosecute the same or similar claims in the future, the Applicants have amended Claim 20 to overcome this objection.

It is also the Applicant's belief that the proposed amendments to the claims obviates the Examiner's rejection with respect to Claims 25 and 26.

Rejection Under 35 USC §112, first paragraph

The Examiner has rejected Claims 1-4 and 20-23 on the ground that the specification, while being enabling for detecting upper and lower gastrointestinal bleeding, does not reasonably provide enablement for a method of diagnosis using any type of biological sample.

The Applicants would like to point out and emphasize that the invention, as disclosed in the pending application, is not directed solely towards detecting gastrointestinal tract bleeding

but, rather, the detection of gastrointestinal tract bleeding only represents a preferred embodiment of the present invention and is not intended to be a limitation on the scope of the biological samples which can be tested utilizing the method and test strips of the present invention. Since it is not necessary under current U.S. patent law to exemplify each and every embodiment of the claimed invention, the Applicants believe that the exemplification provided in the context of gastrointestinal bleeding is sufficient to support the notion that blood can be detected by the method of the present invention in the context of any biological samples. Therefore, the Applicants believe that the rejected Claims are enabled by the pending specification and the rejection should be withdrawn.

In relation to the Examiner's specific comments with respect to Claims 25 and 26, we believe that the amendments proposed to the claims overcome this objection.

Rejection Under 35 USC §103

The Examiner has rejected claims 1-4, 6-11, 13-17 and 19-23 as being obvious in light of Barrows *et al.* (1978) when considered in light of US Patent No. 6,436,721 (to Kuo, *et al.*, and International Patent Publication No. WO98/33069 (to Sy). This rejection is respectfully traversed.

Barrows, *et al.*, teach an immunochemical test that exhibits increased sensitivity for human hemoglobin over purely chemical tests such as guaiac. Specifically, the test is a radial immunodiffusion assay, which involves the overnight incubation of the sample on agarose gel plates containing goat anti-human hemoglobin serum. Barrows, *et al.*, compared the results from this assay with results obtained using the guaiac peroxidase method and demonstrated that the radial immunoassay had an increased sensitivity. They reference to the identification of globin and heme as separate components of the sample. If antibodies to hemoglobin as a whole are used there would be no possible way to distinguish whether or not the gastrointestinal tract bleeding was in effect upper or lower. Hence, in the Applicants' opinion, Barrow's technique is not directed to the problems associated with the prozone phenomenon nor to an assay which is able to distinguish between upper and lower intestinal track bleeding but, rather, to the problems associated with contaminants which may be present in the stool such as plant peroxidases, animal blood peroxidases and ascorbic acid.

US Patent 6,436,721 discloses a means for quantifying analytes, which are assessed via use of a chromatographic test strip. WO98/33069 discloses an assay device, which can be utilized in the context of many different types of immunoassays. Specifically, this latter application describes a device which appears to achieve the absorption and unidirectional flow of an analyte. Both these citations merely disclose means and/or devices for performing improved unidirectional chromatography but provide no further information which, when considered together with Barrows, *et al.* (1978), would render obvious the notion of differentiating upper versus lower gastrointestinal tract bleeding; nor the notion of how one would design a chromatographic test strip for separately and specifically detecting the heme and globin components of hemoglobin utilizing the combined immunochemical/chromogen based assay. The improvements which are disclosed in these two prior art documents can be applied or used with respect to any test device which requires unidirectional chromatography to occur. However, Applicants' invention lies not with the notion of performing unidirectional chromatography but, rather, with the notion of detecting upper versus lower gastrointestinal tract bleeding based on the unique design of the test strip of the present invention and the combination of analytes for which it screens.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,

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